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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: October 31, 2007

(use as many sheets as necessary)

Sheet 1 of 5

Complete If Known

Application Number	10/035,324
Filing Date	01/04/2002
First Named Inventor	H. William Bosch
Art Unit	1616
Examiner Name	Mina Haghighatian
Attorney Docket Number	029318-0107

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	C1	6 464 958 B1	10/15/2002	BERNINI et al.	
	C2	4 807 814	2/28/1989	DOUCHE et al.	
	C3	5 118 528	6/2/1992	FESSI et al.	
	C4	5 202 110	4/13/1993	DALBY et al.	
	C5	5 225 183	7/6/1993	PUREWAL et al.	
	C6	5 260 478	11/9/1993	BACON et al.	
	C7	5 264 610	11/23/1993	BACON et al.	
	C8	5 300 739	4/5/1994	BITTAR	
	C9	5 322 679	6/21/1994	BACON et al.	
	C10	5 518 738	5/21/1996	EICKHOFF et al.	
	C11	5 785 049	7/28/1998	SMITH et al.	
	C12	5 985 309	11/16/1999	EDWARDS et al.	
	C13	6 811 767	11/2004	BOSCH et al.	
	C14	5 192 528	3/1993	RADHAKRISHNAN et al.	
	C15	6 264 922	7/2001	WOOD et al.	
	C16	6 811 767	11/2004	BOSCH et al.	
	C17	5 747 001	5/1998	WIEDMANN et al.	
	C18	5 993 781	11/30/1999	SNELL et al.	
	C19	2005/0244503 A1	11/3/2005	RABINOW et al.	
	C20	2005/244339 A1	11/3/2005	Jaernig JURGEN et al.	

FOREIGN PATENT DOCUMENTS

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		WO 02/098565	12/12/2002	ELAN PHARMA INTERNATIONAL LIMITED		
	C21	WO 95/27475	10/19/1995			
	C22	WO 96/25918	8/29/1996			
	C23	WO 98/35666	08/20/1998			
	C24	WO 99/30687	06/24/1999			
	C25	WO 99/38493	08/05/1999			
	C26	WO 99/45779	09/16/1999			
	C27	EP 0 275 796	07/27/1998			
	C28	EP 0 347 779	12/27/1989			
	C29	EP 0 499 299 A2	08/19/1992			
	C30	EP 0 262 560	04/06/1998			
	C31	WO 92/18105	10/29/1992	SANDOZ LTD.		
	C32	WO 96/25921	08/29/1996	NANOSYSTEMS L.L.C.		

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	C33	WO 96/22766	08/01/1996	NANOSYSTEMS L.L.C.		
	C34	WO 96/00567	01/11/1996	EASTMAN KODAK COMPANY		
	C35	WO 95/31974	11/30/1995	EASTMAN KODAK COMPANY		
	C36	WO 94/02122	02/03/1994	UNIVERSITY OF NOTTINGHAM		
	C37	EP 0 600 528	06/08/1994	ELAN PHARMA INTERNATIONAL LIMITED		
	C38	EP 0 717 122 A	10/18/2006	PARI GMBH		
	C39	WO 99/32156 A	7/1/1999	BAYER AG		
	C40	GB 1 149 648 A	4/23/1969	MERCK & CO. INC.		
	C41	WO 99/25359 A	5/27/1999	KRISTIN et al.		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	C42	Stephen P. Newman, Chapter 9, "Therapeutic Aerosols," in Aerosols and the Lung, Clarke et al., eds., pp. 197-224 (Butterworths, London, England, 1984)	
	C43	Prodi et al., "Airborne Particles And Their Intrapulmonary Deposition", in Scientific Foundations Of Respiratory Medicine, J. G. Scadding ed., pp. 545-558 (W.B. Saunders Co., Philadelphia, PA 1981)	
	C44	J. Heyder, "Mechanisms Of Aerosol Particle Deposition", Lung Mucociliary Clearance, 80(6):820-823 (1981)	
	C45	Fox et al., "Performance Of A Venturi Eductor As A Feeder In A Pneumatic Conveying System," Powder And Bulk Engineering, pp. 33-36 (1988)	

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✓	C46	Tiano, "Functionality Testing Used To Rationally Assess Performance Of A Model Respiratory Solution Or Suspension In A Nebulizer (Performance Assessment)," Vol. 56/12-B of Dissertation Abstracts International (1995)		
✓	C47	Waldrep et al., "Operating Characteristics of 18 Different Continuous-Flow Jet Nebulizer With Beclomethasone Dipropionate Liposome Aerosol," Chest, 105(6):106 (1994)		
✓	C48	P. Byron, "Aerosol Formulation, Generation, And Delivery Using Normetered Systems," Respiratory Drug Delivery, 144-151 (CRC Press, 1989)		
	C49	Soviet Union Patent No. 628930, for "Bulb-Actuated Ejector For Powdered Medicinal Substance" (1978)		
	C50	F. Moren, Chapter 13, "Aerosol Dosage Forms and Formulations," Aerosols in Medicine: Principles, Diagnosis and Therapy, 2nd Edition, F. Moren et al. eds. (Elsevier Science Publishers 1993)		
✓	C51	Remington's Pharmaceutical Sciences, pp. 1565-1567 (Mack Publishing Company 1990)		
✓	C52	Edwards et al., "Large Porous Particles for Pulmonary Drug Delivery," Science, 276:1868-1871 (June 20, 1997)		
✓	C53	"Test Method B527-93(2000)el Standard Test Method for Determination of Tap Density of Metallic Powders and Compounds," http://www.astm.org/DATABASE.CART/PAGES/B527.htm		

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✓	C54	"Autotap and Dual Autotap," http://www.quantachrome.com/Density/Autotap.htm	
✓	C55	"Optimal Tapped Density Tester," http://optimalcontrol.com/tapped.html	
	C56	KIRBY ET AL., "Liposomes," <i>Encyclopedia of Controlled Drug Delivery</i> , Vol. 1, John Wiley & Sons, 1999, pp. 461-473.	
	C57	VOIGHT, <i>Pharmazeutische Technologie</i> , 7 th Edition, Ulstein Mosby, 1993, pp. 181-182.	
	C58	STRICKER (Ed.), <i>Physikalische Pharmazie</i> , 3 rd Edition, Wissenschaftliche Verlagsgesellschaft Stuttgart, 1987, pp. 27-28.	
	C59	CRAIG ET AL., "The relevance of the amorphous state to pharmaceutical dosage forms: glassy drugs and freeze dried systems," <i>International Journal of Pharmaceutics</i> , 179(1999), pp. 179-207.	
	C60	LACY ET AL., <i>Drug Information Handbook</i> , LEXI-COMP, INC., (1993), pp. 95-96.	
	C61	Non Final Office Action USSN 11/592,262 dated 9/19/2007.	

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	C62	Non Final Office Action USSN 10/667,472 dated 10/11/2005.	
	C63	Final Office Action USSN 10/667,472 dated 4/6/2006.	
	C64	Non Final Office Action USSN 10/768,194 dated 4/6/2006.	
	C65	Final Office Action USSN 10/768,194 dated 1/29/2007.	
	C66	Non Final Office Action USSN 10/768,194 dated 10/15/2007.	

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